

FOOD AND DRUG ADMINISTRATION

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MEDICAL DEVICES ADVISORY COMMITTEE

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ORTHOPAEDIC AND REHABILITATION DEVICES
ADVISORY PANEL

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MEETING

OPEN SESSION

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FRIDAY,
FEBRUARY 18, 2000

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The panel met at 9:00 a.m., in Room 020B
of the Center for Devices and Radiological Health,
9200 Corporate Boulevard, Rockville, Maryland,
Dr. Barbara D. Boyan, Chairperson, presiding.

PRESENT:

BARBARA D. BOYAN, Ph.D., Chairperson
ALBERT J. ABOULAFIA, M.D., Voting Member
MARCUS P. BESSER, Ph.D., Temp. Voting Member
JENS R. CHAPMAN, M.D., Temp. Voting Member
THOMAS B. DUCKER, M.D., Temp. Voting Member
CATO T. LAURENCIN, M.D., Ph.D., Voting Member
HARRY B. SKINNER, M.D., Ph.D., Voting Member
JANET WITTES, Ph.D., Temp. Voting Member
MICHAEL J. YASZEMSKI, M.D., Ph.D., Voting
Member
HANY DEMIAN, M.S., Executive Secretary

FDA:

JAMES E. DILLARD
ARIC KAISER
MARK N. MELKERSON

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PRESENT: (CONT.)

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TEENA AUGOSTINO
JOHN BURKHART, PH.D.
REGINALD DAVIS, M.D.
MICHAEL HISEY, M.D.
DAVID HOOPER, Ph.D.
ERIK WAGNER

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P-R-O-C-E-E-D-I-N-G-S

(9:07 a.m.)

MR. DEMIAN: I want to thank everybody for coming, you know, when we had such inclimate weather. It's great that we will still be able to do this.

So we're ready to begin this meeting of the Orthopaedic and Rehabilitation Devices Panel. My name is Hany Demian. I'm the Executive Secretary of this panel, and I'm a senior orthopedic reviewer in the Orthopedic Devices Branch.

I would like to remind everyone that you are requested to sign in on the attendance sheets. You may also pick up an agenda and information about today's meeting, including how to find out about future meeting dates through the Advisory Panel phoneline and how to obtain meeting minutes or transcripts.

I will now read two statements that are required to be read into the record -- the deputization of temporary voting member statement and the conflict of interest statement.

Appointment to temporary voting status. Pursuant to the authority granted under the Medical Device Advisory Committee charter dated October 27, 1990, as amended April 18, 1999, I appoint the

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1 following people as voting members of the Orthopaedic
2 and Rehabilitation Devices Panel for this meeting on
3 February 18, 2000 -- Marcus Besser, Janet Wittes, Jens
4 Chapman, and Thomas Ducker.

5 For the record, these people are special
6 government employees and are consultants to the panel
7 under the Medical Device Advisory Committee. They
8 have undergone customary conflict of interest review
9 and have reviewed the material to be considered at
10 this meeting.

11 Conflict of interest statement. The
12 following announcement addresses conflict of interest
13 issues associated with this meeting and is made part
14 of the record to preclude even any appearance of any
15 impropriety. To determine if any conflict existed,
16 the agency reviewed the submitted agenda for this
17 meeting and all financial interests reported by the
18 committee participants.

19 The conflict of interest statute prohibits
20 special government employees from participating in
21 matters that could affect their or their employer's
22 financial interest.

23 However, the agency has determined that
24 the participation of certain members and consultants,
25 the need for whose services outweigh the potential

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1 conflict of interest involved, is in the best interest
2 of the government. Therefore, waivers have been
3 granted for Drs. Barbara Boyan, Cato Laurencin, Harry
4 Skinner, and Jens Chapman, for their interest in firms
5 that could potentially be affected by the panel's
6 recommendation.

7 Copies of these waivers may be obtained
8 from the agency's Freedom of Information Office,
9 Room 12A-15 of the Parklawn Building.

10 We would also like to not for the record
11 that the agency took into consideration other matters
12 regarding Drs. Yaszemski, Ducker, Boyan, and Chapman.
13 Each of these panelists reported financial interest in
14 firms at issue, but in matters that are not related to
15 today's agenda. The agency has determined, therefore,
16 that they may participate fully in all discussions.

17 In the event that the discussions involved
18 any other products or firms not already on the agenda,
19 for which an FDA participant has a final interest, the
20 participant should excuse him or herself from such
21 involvement, and the exclusion will be noted for the
22 record.

23 With respect to all other participants, we
24 ask, in the interest of fairness, that all persons
25 making statements or presentations disclose any

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1 current or previous financial involvement with any
2 firm whose products they may wish to comment upon.

3 Before turning this meeting over to Dr.
4 Boyan, I would like to introduce our distinguished
5 panel members who have generously given their time to
6 help FDA in matters being discussed today, and other
7 FDA staff seated at this table.

8 So we'll just go around the room, have
9 everybody introduce themselves, tell where they're
10 from and areas of interest.

11 Dr. Boyan?

12 CHAIRPERSON BOYAN: Dr. Barbara Boyan.
13 I'm Professor of Orthopedics and Director of
14 Orthopedic Research as well as Director of the Center
15 for the Enhancement of the Biology/Biomaterials
16 Interface at the University of Texas Health Science
17 Center at San Antonio. And my specialty is bone
18 biology, bone and cartilage biology.

19 DR. YASZEMSKI: Michael Yaszemski. I'm an
20 Orthopedist and Chemical Engineer at the Mayo Clinic
21 in Rochester, Minnesota. My laboratory investigates
22 degradable polymers for bone regeneration. My
23 clinical practice is spine surgery and adult
24 reconstructive surgery.

25 DR. LAURENCIN: I am Dr. Cato Laurencin.

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1 I'm a Professor of Chemical Engineering at Drexel
2 University and a Clinical Professor of Orthopedic
3 Surgery at MCP Hanneman University. I direct the
4 Center for Advanced Biomaterials and Tissue
5 Engineering at Drexel University, and my clinical
6 interests are in shoulder and sports.

7 DR. SKINNER: My name is Harry Skinner,
8 and I'm a Professor of Mechanical and Aerospace
9 Engineering at the University of California-Irvine;
10 also, Professor and Chair of Department of Orthopedic
11 Surgery at U.C.-Irvine. And my clinical interests are
12 joint replacements. My research interests include
13 gait analysis, materials science, that sort of thing.

14 MR. DILLARD: Jim Dillard. I'm the Acting
15 Director in the Division of General and Restorative
16 Devices in the Office of Device Evaluation, Center for
17 Devices and Radiological Health. And I'm interested
18 in all medical devices that are under my purview.

19 DR. WITTES: Hi. I'm Janet Wittes. I'm
20 a statistician. I'm involved mostly in clinical
21 trials of both theory and applications.

22 DR. DUCKER: I'm Tom Ducker. I'm the
23 renegade neurosurgeon here. I am in practice in
24 Annapolis, take care of people, and have professorship
25 ties back to Hopkins and Maryland.

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1 DR. CHAPMAN: My name is Jens Chapman from
2 the other Washington, Washington State that is. I'm
3 an Associate Professor of Orthopedic Surgery at the
4 University of Washington and an Adjunct Associate
5 Professor in Neurosurgery there. And I'm the Chief of
6 the Spine Service, and my interest is in spine
7 surgery.

8 DR. ABOULAFIA: My name is Albert
9 Aboulafia. I'm an Orthopedic Surgeon. My area of
10 interest is orthopedic gynecology, large-segment bone
11 defects, and bone replacement. I'm now with the
12 University of Maryland and Sinai Hospital in
13 Baltimore.

14 DR. BESSER: Marcus Besser. I'm Assistant
15 Director of the Human Performance Lab and an Associate
16 Professor in Physical Therapy at Thomas Jefferson
17 University in Philadelphia. My background is in
18 biomechanics, gait analysis, and that stuff. And my
19 research interests are in posture, balance, and falls.

20 MR. DEMIAN: Thank you.

21 At this time, I would like to turn the
22 meeting over to our Chairperson, Dr. Barbara Boyan.

23 Jim, did you introduce yourself? Okay.

24 CHAIRPERSON BOYAN: Good morning. My name
25 is Dr. Barbara Boyan. I'm the Chairperson for this

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1 meeting.

2 I would like to note for the record that
3 the voting members present constitute a quorum, as
4 required by 21 CFR Part 14.

5 First, Mr. Mark Melkerson, Branch Chief of
6 the Orthopedic Devices Branch, will provide us with an
7 update.

8 MR. MELKERSON: Good morning. I'm Mark
9 Melkerson, Branch Chief of Orthopedic Devices. This
10 is going to be very brief.

11 In terms of keeping the panel posted with
12 what we've been doing in the previous panel meetings,
13 there will be a draft FR notice for the panel
14 recommendation to reclassify the constrained total hip
15 arthroplasty. We're currently working on that, along
16 with our influx of new devices.

17 Also, we've received a lot of positive
18 feedback on the panel's discussion from the
19 development of computer controlled systems, whether it
20 be surgical assist or actual surgical devices.

21 The final order for reclassification of
22 polymethyl methacrylate bone cements and the non-
23 constrained and semi-constrained shoulders were
24 issued. Actually, there should be two dates there, I
25 apologize. PMMA was December 17, 1999. The

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1 constrained shoulders was October 17, 1999.

2 Division staffing -- as Jim identified he
3 is continuing to act as Division Director of General
4 and Restorative Devices. Dr. Celia Witten, our
5 Division Director, is still acting as Division
6 Director for Cardiovascular and Respiratory Devices
7 until that vacancy is filled.

8 Within the Orthopedic Devices Branch, Ms.
9 Jodi Nashman is continuing as our bone and joint
10 replacement team leader. I'm filling in, at least
11 through the end of the Academy meeting when we do a
12 rotation, for the spinal and osteosynthesis devices.

13 Returning to our fold, Janine Morris, a
14 Mechanical Engineer, is back after a detail with our
15 post-market surveillance group, as well as our Office
16 Director. And a new reviewer to our staff -- his
17 background is -- academically, it's chemist, but his
18 specialty area is bone substitutes and bone joint
19 replacement. No, excuse me, fillers, coatings.

20 And with that, I'm completed.

21 CHAIRPERSON BOYAN: Thank you, Mr.
22 Melkerson.

23 We will now proceed with the open public
24 hearing session of this meeting. I would ask at this
25 time that all persons addressing the panel come

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1 forward and speak clearly into the microphone as the
2 transcriptionist is dependent on this means of
3 providing an accurate record of this meeting.

4 We are requesting that all persons making
5 statements during the open public hearing of the
6 meeting disclose whether they have financial interest
7 in any medical device company. Before making your
8 presentation to the panel, in addition to stating your
9 name and affiliation, please state the nature of your
10 financial interest, if any.

11 Is there anyone wishing to address the
12 panel? If you want to address the panel in the open
13 public hearing portion, you should raise your hand.

14 Seeing none, we will now proceed to the
15 closed portion of the meeting. So if anybody that is
16 not directly related to the PDP that we're about to
17 discuss would please leave the room.

18 (Whereupon, at 9:20 a.m., the Open Session
19 was concluded and the meeting went immediately into
20 Closed Session.)
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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: MEETING - OPEN SESSION

Before: ORTHOPAEDIC AND REHABILITATION
DEVICES ADVISORY PANEL

Date: FEBRUARY 18, 2000

Place: ROCKVILLE, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.

Rebecca Davis